

IQ/OQ/IPV service for Ion Torrent instruments

Helping you get into production faster

No one understands your Ion Torrent™ instruments better than the people who design, develop, and support them. When you use our qualification services, trained and certified engineers from Thermo Fisher Scientific will conduct Installation Qualification (IQ), Operational Qualification (OQ), and Instrument Performance Verification (IPV) as part of your overall system validation.

Help verify instrument accuracy and reduce your risk and workload

Our compliance services for Ion Torrent instruments help you bring your next-generation sequencing (NGS) lab into production faster. Depending on your requirements, these services may be necessary to comply with global standards (e.g., ISO 17025 and ISO 15189), country-specific regulations (e.g., US FDA 21 CFR Part 11), and other laboratory standards. All services come with audit-ready documentation.

Qualify your entire workflow

Library preparation	Sequencing systems			
	Ion S5™	Ion S5™ XL	Ion PGM™	Ion Proton™
Ion Chef™	✓	✓	✓	✓
Ion OneTouch™ 2	✓	✓	✓	✓

Our qualification protocols cover the entire NGS workflow from template preparation through sequencing, helping you be audit-ready.

It is important to regularly have your instruments checked and formally tested to confirm they are working according to manufacturer's specifications and identify possible impact due to normal wear or inadequate user maintenance. The IQ/OQ/IPV service is recommended to verify:

- The operation of a newly installed Ion Torrent instrument
- The operation of a previously verified Ion Torrent instrument that has undergone repair or maintenance that is critical to the performance of the system
- The operation of an Ion Torrent instrument that has site requirements for a scheduled operation qualification
- Additions, exchanges, or upgrades that may affect data results of an Ion Torrent instrument

IQ/OQ/IPV tests

Our engineers have extensive experience and knowledge of our instruments and systems. The comprehensive IQ/OQ/IPV service includes the following:

- Order and System Verification to verify that the instrumentation ordered was received and fully documented
- Documentation Verification to verify that documentation is recorded
- Installation Verification to verify that the installation meets specifications
- Software Identification Verification to document current versions and verify compatibility
- Maintenance Verification to verify that standard operating procedures (SOPs) for maintenance exist
- Customer Training Verification to verify that customers are trained on the basic operation and use per manufacturer's specifications
- Certifications for test equipment and field service engineers
- Record that instrument is installed in a suitable environment for operation
- Verification of hardware to verify it functions according to manufacturer's specifications upon installation
- Verification of instrument sequencing performance using validated test samples
- System Verification to verify and record that all major subsystems meet their individual operational specifications and that the system powers on properly

Pre-IQ/OQ/IPV recommendations

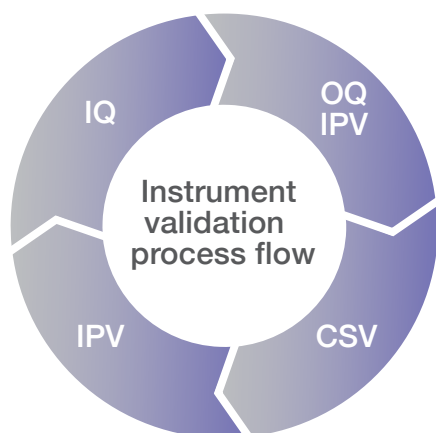
To help maximize the effectiveness of your IQ/OQ/IPV service, we recommend you do the following prior to the service:

- For systems that require routine planned maintenance (PM), we advise you to complete the PM immediately before an IQ/OQ/IPV to ensure system maintenance is up to date
- Review and approve the procedures in accordance with your organizational requirements
- Ensure that your laboratory meets our site preparation requirements
- Check that the Torrent Suite™ Software that will be used to calculate results for the IQ/OQ/IPV test procedures is qualified or validated according to your documented SOPs

Get more value out of your service plans

We offer single-event services for IQ/OQ/IPV. After an IQ/OQ/IPV, choose our AB Complete service plan, which includes qualification after every maintenance and major repair event.

To learn more about our instrument compliance services, please contact your local Thermo Fisher Scientific sales representative or email us at **compliancesales@thermofisher.com**



**IQ/OQ/IPV is an integral part
of the total instrument validation process.**

Qualification services and service plans

One-time qualification service	Workflow	Cat. No.
Installation Qualification/Operational Qualification (IQ/OQ)		
Helps ensure that your instruments are delivered and installed per our specifications. Our IQ/OQ service qualifies your workflow upon installation or after a move. The IQ/OQ service must be purchased prior to the initiation of AB Complete or AB Qualification service contracts.	Ion S5 and Ion Chef Systems	A29081
	Ion S5 XL and Ion Chef Systems	A29236
	Ion PGM and Ion Chef Systems	A26313
	Ion Proton and Ion Chef Systems	A26329
	Ion S5 and Ion OneTouch 2 Systems	A29171
	Ion S5 XL and Ion OneTouch 2 Systems	A29173
	Ion PGM and Ion OneTouch 2 Systems	A26136
	Ion Proton and Ion OneTouch 2 Systems	A26139
Operational Qualification/Instrument Performance Verification (OQ/IPV)		
Verify that your instruments are performing according to manufacturer's specifications at the time of testing. Our OQ/IPV service qualifies your workflow after a major repair or change to your system. OQ/IPV is included after every planned maintenance and critical repair, under the AB Complete and AB Qualification service contracts.	Ion S5 and Ion Chef Systems	A29082
	Ion S5 XL and Ion Chef Systems	A29170
	Ion PGM and Ion Chef Systems	A26141
	Ion Proton and Ion Chef Systems	A26142
	Ion S5 and Ion OneTouch 2 Systems	A29172
	Ion S5 XL and Ion OneTouch 2 Systems	A29174
	Ion PGM and Ion OneTouch 2 Systems	A26137
	Ion Proton and Ion OneTouch 2 Systems	A26140
Service contracts for regulated labs		
AB Complete		
Ideal for laboratories that require the highest level of service, as well as compliance with government and international standards. Qualification services for your instruments and priority next-business-day response* set AB Complete apart from other service plans. This plan also provides on-site application consulting to help optimize a customer's protocols, methodologies, and workflows. Includes one workflow (sample prep and sequencer).	Ion S5 System	ZG21SCIONS5
	Ion S5 XL System	ZG21SCIONS5XL
	Ion PGM System	ZG21SCIONPGMSYS
	Ion Proton System	ZG21SCIONPROTON
	Ion Chef System	ZG21SCIONCHEF
AB Qualification add-on		
This service plan upgrades your AB Assurance plan to include qualification service for your instrument after maintenance and critical repairs.	Ion S5 System	ZGQUSCIONS5
	Ion S5 XL System	ZGQUSCIONS5XL
	Ion PGM System	ZGQUSCIONPGMSYS
	Ion Proton System	ZGQUSCIONPROTON
Extra workflows		
For labs with more Ion OneTouch 2 Systems than sequencers, or for labs that would like to have multiple combinations of Ion Chef System workflows qualified.	Ion Chef System	ZGQUSCIONCHEF
	Ion OneTouch 2 System	ZGQUSCONETOUCH2

* Certain restrictions apply. Contact your services and support representative for details or email compliancesales@thermofisher.com

Find out more at thermofisher.com/complianceservices

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